DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-154/S-035
NDA 20-155/S-026
NDA 20-156/S-027

Bristol-Myers Squibb Company
Attention: Mari-Laure Papi
Associate, Worldwide Regulatory Affairs
5 Research Parkway
Wallingford, CT 06492

10 SEP 2001

Dear Ms. Papi:

Please refer to your supplemental new drug applications dated September 8, 2000, received September 11, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIDEX® and (didanosine) Buffered Tablets, VIDEX® (didanosine) Buffered Powder for Oral Solution, and VIDEX® (didanosine) Pediatric Powder.

We acknowledge receipt of your submissions dated September 11, 2000, and January 23, 2001.

These supplemental new drug applications allow for a reformatting of the **Clinical Pharmacology** and **Precautions, Drug Interactions** sections of the VIDEX® package insert.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted draft labeling (package insert submitted January 23, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Destry M. Sillivan, M.S., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

Debra Birnkrant, M.D.
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research